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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BURKHART, MICHAEL D	
ART UNIT	**PAPER NUMBER**
1633	

MAIL DATE	DELIVERY MODE
05/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/072,036	THASTRUP ET AL.	
	Examiner	Art Unit	
	Michael D. Burkhart	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-72* is/are pending in the application.

4a) Of the above claim(s) *55-72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/17/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt and entry of the amendment dated 3/20/2007 is acknowledged. After entry of the amendment, claims 44-72 are pending. Claims 55-72 are withdrawn as drawn to a non-elected invention (see below). Claims 44-54 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action. Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn.

Election/Restrictions

Newly submitted claim 55-72 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 55-72 recite method steps and reagents not found in the methods of claims 44-54 and thus represent a distinct invention. Claims 55, 56 and 57 recite, in step (a), a cell culture devoid of any compound of a library of compounds, a type of cell culture not found in the methods of claims 44-54. Claims 55, 56 and 57 recite a step of introducing a compound from the library of compounds into the cell culture recited above, a step not found in the methods of claims 44-54 because no such cells are recited in claims 44-54. Furthermore, steps (d) - (f) in claims 55, 56, and 57 are not found within claims 44-54.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 55-72 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

Claim 48 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a new rejection necessitated by applicants' amendment of the claims in the response filed 3/20/2007. This is a New Matter rejection.

Amended claim 48 recites a "synthetic chemical compound". The response does not indicate specifically where in the specification support may be found for the limitation, which is intended to be a narrowing limitation of the compounds recited in the base claims 44-46 (see page 12 of the response dated 3/20/2007). A review of the specification does not reveal any support for "synthetic chemical compounds" as a narrowing limitation of the library of compounds recited in the base claims. In fact, a search of the specification does not reveal use of the word "synthetic." Therefore, there is no support for the limitation "synthetic chemical compound." Thus, the amended claim includes impermissible New Matter.

Claim Rejections - 35 USC § 102

Claims 44-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Carey et al (J. Cell Biol., June 1996, cited by applicants in the IDS of 2/5/2002). **This rejection is maintained for reasons made of record in the Office Actions of 12/1/2005, 10/20/2006, and for reasons set forth below.**

Response to Arguments

Applicant's arguments filed 3/20/2007 have been fully considered but they are not persuasive. Applicants essentially assert that: 1) the interpretation of the term "library of compounds" is overly broad, and that a declaration from Chris Ireland (the Ireland declaration hereinafter) defines the term; 2) according to the Ireland declaration, the consideration of any and all substances used in the methods of Carey et al as a "library of compounds" is incorrect, as only dexamethasone should be considered a compound; 3) screening only dexamethasone, as disclosed by Carey et al, is not to be considered "screening the library of compounds", as recited in the instant claims; 4) screening dexamethasone, as disclosed by Carey et al, is not to be considered screening for "a biological function or biological effect" as recited in the instant claims because the effects of dexamethasone on GR were already known, and that no other compounds were screened for "a biological function or biological effect."

As a first matter, it is reiterated that the specification provides no definition or guidance as to what constitutes a "library of compounds", hence the term is interpreted as broadly reading on a collection of one or more compounds, e.g. the claim language itself suggests a library comprises "a t least one compound", see step (b) of claim 1. Regarding 1)-4) above, a reading of the Ireland declaration reveals nothing more than assertions and the opinion of Mr. Ireland as to the interpretation of the term "library of compounds." Such opinion evidence is generally not probative when unsupported by facts or evidence, §MPEP 716.01(c). Furthermore, "Argument of counsel cannot take the place of evidence lacking in the record." *In re Scarbrough*, 182 USPQ 298, 302 (CCPA 1974). Applicants and the Ireland declaration attempt to define "library of compounds" as a collection of compounds that are either pure or at a known

concentration...arranged such that each compound can be selected from the collection either alone or in combination. This is unconvincing for two reasons: 1) the claim language (e.g. claim 44) clearly recites using "at least one compound of the library" in step (b) and as such encompasses using only one compound; and, 2) DMEM and FBS, as used by Carey et al, are composed of compounds at known concentrations. See the ingredient lists of DMEM as supplied by Gibco BRL (a common supplier of cell culture products such as DMEM) and Hyclone FBS (both lists provided for applicants convenience). DMEM contains over twenty compounds at defined concentrations, including phenol red at 15 mg/L. FBS also contains over twenty compounds at known concentrations, e.g. progesterone and cholesterol. Thus, the cell culture conditions of Carey et al appear to meet applicants definition of a compound library in that the compounds were present at known concentrations, and could be used in combination. If desired to be used alone, they could be purified by well known fractionation methods and/or chromatographic techniques.

Applicants assert that a library of compounds is assembled for the purpose of testing such compounds, and that this defines over the use of the compounds of Carey et al. Such is not the case. This is merely a statement of intended use of a library of compounds, and is not even found as a limitation in the claims. Applicants further assert that screening a library of compounds means a process of systematically examining and testing the compounds of a library of compounds to determine or detect wanted or unwanted attributes. It is considered that Carey et al did so examine the attributes of all the compounds in DMEM (including phenol red) and FBS. The compounds did not have any effect, considered to be an "unwanted attribute" as above. Finally, in response to applicant's argument that the references fail to show certain

features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a library of compounds is assembled for a certain purpose and screening a library comprises a systematic evaluation of the compounds for an attribute) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Regarding 3) and 4) above, again, it is noted that the claim language requires only a single compound of a compound library to be screened. Furthermore, it is considered that the effects of dexamethasone and the compounds in charcoal-stripped serum, at the least, were determined. See page 6 of the previous Office Action.

Regarding 4) above, applicants present no reasoning or evidence that the effect of dexamethasone was known on the GR-GFP molecule. Furthermore, because the other compounds used in the methods of Carey et al did not effect the localization of GR-GFP does not mean they were not screened, it merely means they did not have an effect on GR-GFP localization. This would satisfy the definition of screening compounds as put forth by applicants, i.e. they had "unwanted attributes."

Claim Rejections - 35 USC § 103

Claims 53 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carey as applied to claims 44-52 above, and further in view of Cormack et al (Gene, 1996). **This rejection is maintained for reasons made of record in the Office Actions of 12/1/2005, 10/20/2006, and for reasons set forth below.**

Response to Arguments

Applicant's arguments filed 3/20/2007 have been fully considered but they are not persuasive. Applicants essentially assert that Cormack et al do not cure the deficiencies of Carey et al as set forth above. Such is not persuasive because Carey et al is considered to anticipate claims 44-52 for reasons set forth above, and hence has no deficiencies. Therefore, in view of the combined teaching of the cited prior art of record, the invention as claimed is *prima facie* obvious.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael D. Burkhart
Examiner
Art Unit 1633

SUMESH KAUSHAL, PH.D.
PRIMARY EXAMINER